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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,902	11/03/2006	Egil Jellum	Q-90288	7146

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EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,902	JELLUM ET AL.	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 8-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1-5, 8-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn et al. (US Pat. 5,804, 203) in view of US 5,866,168, Denhem et al., Remington's, Hahn, Decaris et al. and Lambert et al..

Hahn et al. disclose that skin conditions such as psoriasis produce an intrinsic skin irritation (Column 3, lines 35-50). It is disclosed that strontium is effective in suppressing skin irritation due to sources such as chemical and environmental exposure or tissue inflammation, injury or skin pathology (Column 9, lines 13-25). It is disclosed that the amount strontium can be reduced if a skin penetration-enhancing is added (Column 14, lines 54-68). It is disclosed that the strontium cation is combined with a suitable anion, such as nitrate, chloride, bromide, iodide, acetate, amino acids, EDTA, etc. (Column 16, lines 10-38). It is disclosed that the other active ingredients can be added such as anti-acne drugs (Column 19, lines 53-55).

US 5,866,168 disclose that strontium is a substance P antagonist and is effective in the treatment of pain, inflammatory diseases, such as rheumatoid arthritis, psoriasis, acne, etc. (Column 1).

Denhem et al. disclose that radiation therapy cause inflammation of skin tissues (page 132).

Remington's discloses that dimethyl sulfoxide is a permeation enhancer but is also effective as a anti-inflammatory agent (Page 1121).

Hahn discloses that strontium salts suppress both sensory irritation and inflammation, including neurogenic inflammation (Page 693). It is disclosed that neurogenic inflammation is pathogenically important in many irritating and inflammatory conditions such as irritant and

allergic contact dermatitis, psoriasis, atopic dermatitis, astham, rheumatoid arthrtitis, inflammatory bowel disease and other gastrointestinal disorders (page 693).

Decaris et al. disclose that substance P is a well known mediator of neurogenic inflammation and plays a role in the development of rheumatoid arthritis and that local inflammation can produce degenerative articular effects from a distance, through systemic or cellular transmission pathways (pages 1951, 1952, 1957, 1958).

Lambert et al. disclose that rheumatoid arthritis is an autoimmune disease characterized by inflammation of the synovial membrane of multiple joints and that substance P has pro-inflammatory properties (Page 269).

Hahn et al. disclose the use of strontium to treat inflammation. The difference between Hahn et al. and the claimed invention is that Hahn et al. does not expressly disclose the treatment of inflammation with strontium, the use of dimethylsulphoxide (DMSO) as a permeation enhancer and the treatment of inflammation associated with radiation therapy or arthritis. However, the prior art amply suggests the same as Hahn et al. discloses that strontium is effective in treating irritation where one of the causes of irritation include tissue inflammation, Remington's discloses that DMSO is an anti-inflammatory and permeation enhancer, Denham et al. disclose that radiation therapy can cause inflammation of the skin, US Pat. 5,866,168 discloses that strontium is effective in the treating of inflammatory diseases such a rheumatoid arthritis and Hahn discloses that strontium salts suppress both sensory irritation and inflammation. Further, Decaris et al. and Lambert et al. disclose that substance P is pro-inflammatory and mediates the development of rheumatoid arthritis. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that strontium would be effective in treating

various inflammatory conditions including that caused by radiation therapy and rheumatoid arthritis and that DMSO increase the bioavailability of the strontium and provided added anti-inflammatory activity.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Supreme Court in KSR International Co. v. Teleflex Inc., held the following:

(1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;

(2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the filed of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed;

(4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);

(5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396, 1397 (U.S. 2007).

The Applicant argues that there is distinction between the underlying causes or triggers of a disease or condition with happens to be associated with inflammation and treatment of inflammatory process per se. However, the prior art discloses that strontium is a substance P antagonist, as such, the combined teachings of the prior art do disclose treatment of inflammation per se. Further, the prior art also discloses treatment of rheumatoid arthritis, as such, the combined teachings of the prior art also disclose treatment of sub-dermal, soft-tissue inflammation. The Applicant's argument with respect to motivation does not overcome the rejection as motivation is not a required element of the prima facie case of obviousness.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Since the rejection herein is based on a combination of references, there is no requirement that Kahn et al. disclose that strontium is effective against inflammation per se. Also, notwithstanding the amendment regarding sub-dermal and soft-tissue inflammation, the dependent claims are still directed to treatment of inflammation associated with acne vulgaris, psoriasis and radiation therapy, all of which are or include skin conditions.

Kahn et al. does disclose the use of skin penetration enhancer, as such, Kahn et al. is not solely concerned with treatment of irritation on the skin's surface. The Applicant's argument

skin penetration enhancer's are generally present to remove natural skin surface associated products as well as to remove cosmetic products and contaminants is unsupported by evidence. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). Even if true, this still does not avoid the fact that by definition a skin penetration enhancer by definition enhances an agent's penetration through the skin.

As indicated above, there is no requirement that Hahn et al. specifically disclose that strontium is effective treatment of inflammation per se. However, Hahn et al. in view of Hahn does suggest that strontium also functions as an anti-inflammatory. With respect to De Lacharriere (US Pat. 5,866,168), similarly, there is no requirement that said references specifically disclose treatment of inflammation per se as the rejection herein is based on a combination of references. Also, the fact that rheumatoid arthritis is mentioned in the background section of said reference does not overcome the rejection as a reference is prior art for all that it teaches.

The Applicant provides no evidence that strontium does not exert its effects a substance P antagonist or that substance P is not involved in the pathology of this condition. See Decaris et al. and Lambert et al. above. As such, contrary to the Applicant's arguments, the action of strontium on substance P constitutes treatment of inflammation per se.

The Applicant has provided no evidence that one of ordinary skill in the art would not expect strontium applied topically to be effective against sub-dermal inflammation, has provided no evidence that one of ordinary skill in the art would expect that calcium would compete with

strontium and has provided no evidence that one of ordinary skill in the art would expect strontium to have adverse effects similar to calcium which would teach away from using strontium. As indicated above, the arguments of counsel do not constitute evidence.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
May 13, 2009

/John Pak/
Primary Examiner, Art Unit 1616